CORRECTED VERSION*

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :		(11) International Publication Number:
A61B 17/68, A61F 2/44	A1	WO 96/27339
		(43) International Publication Date: 12 September 1996 (12.09.96)

(21) International Application Number: PCT/US96/03226

(22) International Filing Date: 8 March 1996 (08.03.96)

(30) Priority Data:
400,991 8 March 1995 (08.03.95) US

(71) Applicant: ADVANCED MICROBOTICS CORPORATION [US/US]; Suite 200, 2611 S.W. Third Avenue, Portland, OR 97201 (US).

(72) Inventors: SEVRAIN, Lionel, C.; 2, cavée de Rossignol, F-76380 Val-de-la-Haye (FR). BECKETT, Carl, D.; 3508 N.E. 160th Court, Vancouver, WA 98684 (US). SEVRAIN, Christophe, J., P.; 21418 N.W. 11th Avenue, Ridgefield, WA 98642 (US).

(74) Agent: NOONAN, William, D.; Klarquist, Sparkman, Campbell, Leigh & Whinston, One World Trade Center, Suite 1600, 121 S.W. Salmon Street, Portland, OR 97204 (US).

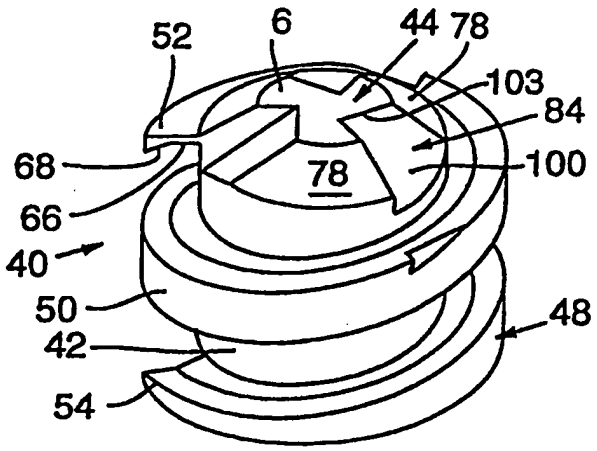
(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: SPINAL DISC IMPLANT

(57) Abstract

A surgical implant (40) for repairing herniated discs includes a cylindrical body (42) with a helical thread (48) around the exterior of the body. The axial width of the thread is less where the thread originates at the cylindrical body than it is at the outer surface (50) of the thread. This radially flared thread cross section enables the threads to firmly interlock with bone, thereby fusing vertebrae together when the implant is screwed into the disc between two vertebrae. The implant has a self-tapping tip that allows the implant to be screwed into a herniated disc and the surrounding bone of the vertebrae without first drilling a threaded hole in the disc to receive the implant. The implant does not require disc curettage, stabilizes the spine by fusing adjacent vertebrae, mimics the functional activity of the lumbosacral spine, and reduces post-operative bleeding by tamponading vessels.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61B 17/68, A61F 2/44

A1

(11) International Publication Number: WO 96/27339

(43) International Publication Date: 12 September 1996 (12.09.96)

(21) International Application Number: PCT/US96/03226

(22) International Filing Date: 8 March 1996 (08.03.96)

(30) Priority Data:
400,991 8 March 1995 (08.03.95) US

(71) Applicant: ADVANCED MICROBOTICS CORPORATION [US/US]; Suite 200, 2611 S.W. Third Avenue, Portland, OR 97201 (US).

(72) Inventors: SEVRAIN, Lionel, C.; 2, cavée de Rossignol, F-76380 Val-de-la-Haye (FR). BECKETT, Carl, D.; 3508 N.E. 160th Court, Vancouver, WA 98684 (US). SEVRAIN, Christophe, J., P.; 21418 N.W. 11th Avenue, Ridgefield, WA 98642 (US).

(74) Agent: NOONAN, William, D.; Klarquist, Sparkman, Campbell, Leigh & Whinston, One World Trade Center, Suite 1600, 121 S.W. Salmon Street, Portland, OR 97204 (US).

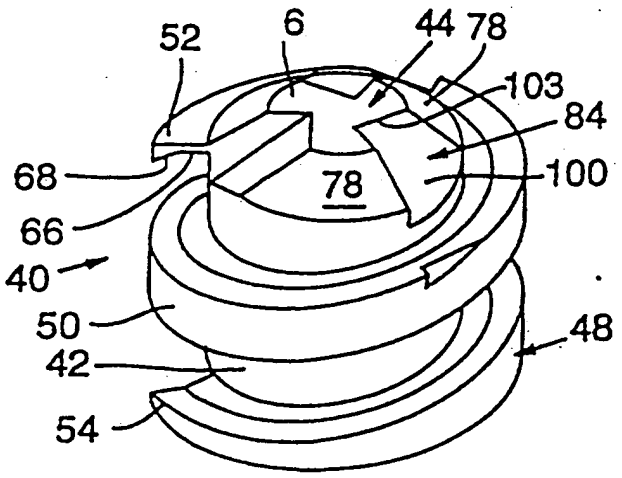
(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: SPINAL DISC IMPLANT

(57) Abstract

A surgical implant (40) for repairing herniated discs includes a cylindrical body (42) with a helical thread (48) around the exterior of the body. The axial width of the thread is less where the thread originates at the cylindrical body than it is at the outer surface (50) of the thread. This radially flared thread cross section enables the threads to firmly interlock with bone, thereby fusing vertebrae together when the implant is screwed into the disc between two vertebrae. The implant has a self-tapping tip that allows the implant to be screwed into a herniated disc and the surrounding bone of the vertebrae without first drilling a threaded hole in the disc to receive the implant. The implant does not require disc curettage, stabilizes the spine by fusing adjacent vertebrae, mimics the functional activity of the lumbosacral spine, and reduces post-operative bleeding by tampon vessels.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgystan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
CS	Czechoslovakia	LT	Lithuania	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	LV	Latvia	TJ	Tajikistan
DK	Denmark	MC	Monaco	TT	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan
GA	Gabon	MR	Mauritania	VN	Viet Nam

SPINAL DISC IMPLANT

Field of the Invention

This invention relates to surgical implants, and more particularly to an implant placed between two spinal vertebrae to fuse them together. It is particularly useful in the surgical treatment of herniated discs.

Background and Summary of the Invention

The spine is a flexible structure that includes thirty-three movable vertebrae. The vertebrae are separated by a fibro-cartilaginous cushion called an intervertebral disc. Many people undergo degeneration of the spine, which produces herniation of the disc from its position between the vertebrae. The herniated disc can impinge on the spinal cord, and nerves leading from the spinal cord, to produce pain and neurological complaints. This condition is sometimes treated by surgery to remove the diseased intervertebral disc.

An intervertebral discectomy is one surgical procedure that may be used to treat intervertebral disc herniations. In this procedure, the affected vertebral bodies are exposed and the intervertebral disc is removed by curettage (discectomy), which eliminates the offending herniating tissue. A second procedure, termed a spinal fusion, may then be required to fix the vertebral bodies together to prevent relative movement therebetween, and re-establish the space originally occupied by the intervertebral disc. Such fixation may cause minor loss of spine flexibility, but this minimal loss of mobility is usually acceptable because the large number of vertebrae in the human spine provide redundant flexibility.

Implants have also been inserted into the intervertebral space during a spinal fusion procedure. The intervertebral implant may be a bone graft removed from another portion of the patient's body, which is known as an autograft. Although bone taken from the

patient's own body helps avoid rejection of the implant, there is always a risk of infection at the donor site. Moreover, the donor site is weakened by the removal of bony material, and is more susceptible to subsequent structural damage as the body ages or undergoes trauma. Other possible sources of graft material for the implant are bone removed from cadavers or other species. These procedures increase the risk of graft rejection, and are particularly undesirable at the present time because of the risk of transmitting deadly infectious diseases, such as the human immunodeficiency virus.

An alternative to the use of a bone graft is to use a manufactured implant made of a synthetic material that is biologically compatible with the body and vertebrae. Examples of such implants are shown in U.S. Patent Nos. 5,015,247, 5,123,926, 5,246,458 and 5,306,307. These implants range from blocks of material designed to resemble an intervertebral disc, to permanent cylindrical implants that are incapable of being removed once surgically implanted in the spine.

Yet another commonly used surgical technique is to remove a cylindrical body of tissue from an intervertebral disc, then place a smooth cylinder into the cylindrical opening. A metal strap is next placed over the opening into which the cylinder has been inserted, and the strap is screwed to adjacent vertebrae to hold the cylinder in place within the intervertebral space. This technique does not effectively fuse the adjacent vertebrae, and suffers from the drawback of allowing subsequent recurrence of the herniated disc through the trephination orifice into which the cylinder was inserted.

It is an object of the present invention to provide an improved spinal implant that avoids the necessity for discal curettage, thereby simplifying the surgery, and shortening the time required in the operating room to complete the surgery.

It is yet another object of the invention to provide such an implant that stabilizes the spine by

fusing the adjacent vertebrae on either side of the herniated disc, and maintains normal intervertebral spacing to avoid post-operative disc pinching.

Yet another object of the invention is to provide an implant that more closely mimics the functional activity of the lumbosacral spine by avoiding vertebral ankylosis from post-operative synostosis.

Yet another object of the invention is to provide an implant that minimizes the risk of injury to large vessels (such as the aorta or vena cava) and other anatomic structures (such as the spinal column), which have, in the past, been damaged during the curettage step when the cylinder of tissue is removed from the intervertebral disc.

Yet another object of the invention is to reduce the risk of post-operative extradural hematoma by helping eliminate hemorrhage which sometimes results from abrasion of the vertebral plates above and below the herniated disc during curettage.

Yet another object of the invention is to provide an implant that tamponades epidural veins, to further reduce the likelihood of hemorrhagic complications.

Even yet another object of the invention is to minimize the risk of hernial recurrence.

In accordance with a preferred embodiment of the present invention, these and other objects of the invention are achieved by providing a self-tapping, threaded prosthetic implant, which includes a substantially cylindrical body with a proximal driving end a distal tip end. The implant further includes a thread extending from the cylindrical body, such that the axial width of the thread where it adjoins the cylindrical body is less than the axial width of the thread at a location radially displaced from the cylindrical body. This progressively increasing axial width of the thread provides a flared thread that helps interlock the thread with bone, and thereby locks the bone to the threads of the implant. The width of the

thread tapers toward the tip of the implant, and one or more beveled edges are present on the tip such that the implant is self-tapping.

In a disclosed embodiment, the implant comprises a body having a longitudinal axis, a proximal driving end, and a distal tip with a flat or non-sharp surface. The body tapers along an annular shoulder to the flat surface, to provide a blunt nose that is atraumatic, non-cutting, and that will not puncture internal organs if the tip is rotated against the organs. A continuous helical thread extends around the body, and the width of the threads flares as the thread radially extends away from the body. The flared width of the thread diminishes as the thread approaches the distal tip, to present a flat leading surface, at a leading edge of the thread, which is perpendicular to the longitudinal axis of the body. The implant is preferably a sterilized implant (for example having been sterilized in an autoclave) for surgical placement in the body. The body of the implant does not extend radially beyond the helical thread around the body.

At least one beveled surface in the shoulder extends across and intersects the leading edge. The beveled surface is in an imaginary plane which is steeper than the shoulder and which intersects the longitudinal axis of the body. In a disclosed embodiment, there are three such beveled surfaces in the shoulder that are equally placed around the circumference of the annular shoulder.

The proximal driving end of the implant has a recess, preferably polygonal in cross-section, into which a surgical driving instrument having a complementary polygonal cross-section is inserted to rotate the instrument. The recess preferably extends at least about half way from the proximal end to distal tip, so that the implant will tend to be retained on the instrument.

The invention also includes a method of inserting the implant between the vertebrae of a patient

who has an intervertebral disc herniation. The method includes making a surgical incision through tissue overlying the diseased disc to gain access to the intervertebral space, and positioning the tip of the self-tapping threaded implant over the area of disc herniation. The implant is then rotated to advance the implant into the disc between the vertebrae, and the flared thread of the implant engages the vertebral bodies above and below the herniated disk. The implant thereby fills the space formerly occupied by the herniated disc material, and fuses the adjacent vertebrae together.

Brief Description of the Drawings

Fig. 1 is a top perspective view of the threaded implant of the present invention.

Fig. 2 is a bottom perspective view of the implant of Fig. 1.

Fig. 3 is a top view of the implant of Fig. 1.

Fig. 4 is a side elevational view taken along view lines 4-4 of Fig. 3.

Fig. 5 is a bottom view of the implant taken along view lines 5-5 of Fig. 4.

Fig. 6 is a top view of the implant.

Fig. 7 is a side elevational view taken along view lines 7-7 of Fig. 6.

Fig. 8 is a top view of the implant, similar to Fig. 6, but with the implant rotated 120° from its position shown in Fig. 6.

Fig. 9 is a side view taken along lines 9-9 of Fig. 8.

Fig. 10 is a view of the implant similar to Fig. 8, but with the implant rotated 120° around its longitudinal axis.

Fig. 11 is a view taken along lines 11-11 of Fig. 10.

Fig. 12 is a schematic, cross-sectional view of the implant in place between two adjacent vertebrae, with a driving member inserted in the implant.

Fig. 13 is an enlarged, cross-sectional view of a portion of the thread on the implant.

Fig. 14 is a schematic, side elevational view of a human spine.

Detailed Description of a Preferred Embodiment

A human spine 20 is depicted in Fig. 14. The spine 20 is formed from thirty-three individual vertebrae 22, with the twenty-four upper vertebrae in most cases separated by intervertebral discs 24. The spine 20 has an anterior aspect 26 and a posterior aspect 28. It is divided into an uppermost cervical portion, intermediate thoracic spine, and lower lumbar and sacral spine.

The present invention is particularly well adapted for surgical treatment of lumbar disc rupture, in the lower portion of the spine. As is well known, each of the uppermost vertebrae is separated by a pulp-like intervertebral disc. When the intervertebral disc herniates, a fragment of the disc either extrudes completely from its intervertebral space, or erupts through the annulus fibrosis and is incarcerated beneath a distended or partially torn posterior longitudinal ligament. Surgery for removal of the extruded disc material usually requires incision of the deep paravertebral fascia lateral to the spinous processes and retraction of the fascia medially over the spine to permit dissection of paravertebral muscles, beginning at the midline. Rupture at the L5-S1 disc, for example, would require exposure of the upper sacrum and all of the L-5 hemilamina. The hemilamina of L-5 would be removed with rongeurs above the superior margin of the ligamentum flavum to expose the dura mater and overlying epidural veins. Once the ligamentum flavum is excised away from its attachment to the sacrum, bone excision is accomplished in the conventional fashion. Further details concerning the conventional surgery for herniated discs may be found, for example, in *Lumbar Spine Surgery--Techniques and Complications* by White et al., C.V. Mosby Company, St. Louis (1987).

Once the herniated disk is surgically exposed, herniated material may be removed to avoid impingement of the herniated material on adjacent nerves. The spinal implant of the present invention may then be introduced into the area previously occupied by the pulp-like material of the disc that has herniated from between the two vertebral bodies. This avoids the delicate and dangerous step of performing a discectomy by curettage of remaining disc material from the intervertebral space. Curettage sometimes produces morbidity, because anterior insertion of the sharp cutting instrument can result in perforation of critical anatomic structures in front of the spine, such as the aorta and vena cava. Hence avoidance of curettage is an important advance over the prior art.

A threaded spinal implant 40 according to the depicted embodiment of the present invention includes a substantially cylindrical body 42 extending axially between a tip end 44 (Fig. 1) and a driving end 46 (Fig. 2). A spiral thread 48 extends around the exterior surface of body 42, and defines a continuous spiral surface or ribbon 50 that is coextensive with a surface of an imaginary cylinder with the same axis as the axis of body 42. The surface 50 preferably has a maximum axial width (in the direction extending from the tip 44 to end 46) of at least about 2 mm. The width of the surface 50 tapers toward each end 44, 46 of the implant to form a sharp leading edge 52 and trailing edge 54 at the respective ends of the implant 40. The depicted implant is formed of titanium, although a number of other suitable materials are known to artisans in this field (e.g. ceramic, stainless steel, tantalum pentoxide, etc.).

The width of thread 48 increases as the thread extends radially outwardly from body 42. This is best seen in Fig. 13, where the thread in cross-section flares as it extends radially away from body 42. The continuous thread 48 has an upper surface and lower surface that meet at surface 50. The upper surface is

compound, in that it includes a first segment 60 that extends substantially perpendicular to a plane through the longitudinal axis of body 42, and a second segment 62 with a surface that extends at an angle alpha of about thirty degrees to surface 60. Similarly, the lower surface of thread 48 is compound, with a first segment 66 perpendicular to a plane through the longitudinal axis of body 42, and a second segment 68 with a surface that extends at angle beta of about thirty degrees to the surface of first segment 66. Hence surfaces 60, 66 are parallel to one another, and surface 50 is parallel to the longitudinal axis of body 42.

Continuous spiral surface 50 extends between and interconnects segments 62, 68. In the disclosed preferred embodiment, segments 60, 62, 66, 68 are each about 0.5 mm in length, such that the overall length of thread 48 extends almost approximately 1 mm from the surface of the implant body. As best seen in the cross-section of Fig. 13, the profile of the thread 48 is flared as the thread extends radially away from body 42. This configuration enables the threads to lock the bone to the thread, and thereby interlocks adjacent vertebral bodies in a manner described below.

The cross-sectional configuration of the thread differs at the leading edge 52 of thread 48, as best seen in Fig. 1. As the axial width of the thread tapers in the direction of the leading edge 52, the angle alpha between segments 60, 62 gradually diminishes until the segments 60, 62 lie in the same plane perpendicular a plane through the longitudinal axis of body 42. The angle beta between segments 66, 68 is, however, maintained. In this manner, the width of thread 48 tapers to a sharp cutting edge that helps introduce the implant into hard bone as the implant is screwed in place.

Similarly, the cross-sectional configuration of the thread differs at the trailing edge 54. As the axial width of the thread tapers in the direction of the

trailing edge 54, the angle alpha between segments 66, 68 gradually diminishes until the segments 66, 68 lie in the same plane perpendicular to a plane through the axis of body 42. The angle alpha between segments 60, 62 is however maintained. In this manner, the width of thread 48 tapers to a sharp trailing edge.

The disclosed implant 40 also has a self-tapping feature that helps avoid the necessity of drilling a cylindrical cavity in the disc material or vertebrae, or inscribing threads within a cylindrical orifice. The distal or tip end 44 tapers to a snub nosed surface 76, which is perpendicular to the longitudinal axis of body 42. The diameter of surface 76 is less than the diameter of body 42, and the diameter of body 42 tapers to surface 76 along a frustoconical shoulder 78. The shoulder 78 slopes at about forty-five degree angle to surface 76. Three beveled indentations 80, 82, 84 are provided in the shoulder 78 as part of the self-tapping feature of the implant 40.

Indentation 80 is provided immediately adjacent leading edge 52, such that the indentation is encountered immediately before leading edge 52 impinges bone as implant 40 is rotated clockwise (as viewed from driving end 46 during insertion of the implant). Indentation 80 includes a first planar surface 86 that intersects the longitudinal axis of body 42, and a second planar surface 88 that is perpendicular to surface 86. The longitudinal axis of body 42 (see Figs. 4 and 9) lies in the plane that contains surface 88. Surface 86 extends partially on to surface 76, where the surface terminates along an edge 89 perpendicular to edge 88, as shown in Fig. 3. The leading edge 90 of indentation 80 is formed by the intersection of surfaces 76, 86. Surface 86 lies in a plane that intersects the axis of body 42 at an included angle of about forty degrees.

Indentation 82 is spaced at about 120 degrees rotation from indentation 80, such that the indentation is encountered after leading edge 52 has already been

rotated into vertebral bone. Indentation 82 includes a first planar surface 92, and a second planar surface 94 that is perpendicular to surface 92. The longitudinal axis of body 42 lies in the plane that contains surface 94 (see Figs. 6 and 7). Surface 92 extends partially on to surface 76, where the surface terminates along an edge 95 perpendicular to surface 94, as shown in Fig. 3. The edge 95 is formed by the intersection of surfaces 76, 92. Surface 92 extends through thread 48 (Fig. 7) and terminates at the apex of the flared thread along surface 68. Surface 92 lies in a plane that intersects body 42 at an included angle of about thirty degrees.

Indentation 84 is spaced about 120 degrees rotation from indentations 80 and 82. Indentation 84 includes a first planar surface 100 (Figs. 6 and 7), and a second planar surface 102 that is perpendicular to surface 100. The longitudinal axis of body 42 (see Figs. 8 and 9) is contained in the plane in which surface 102 lies. Surface 100 extends partially on to surface 76, as shown in Fig. 3, and lies in a plane that intersects body 42 at an included angle of about thirty degrees. An edge 103 is formed at the intersection of surfaces 76, 100.

As best seen in Fig. 3, the planes that contain surfaces 88, 94, 102 all intersect at the axis of body 42, and are separated from each other by 120 degrees.

The driving end 46 of implant 40 contains a hexagonal recess 106 that extends approximately one-half the axial length of body 42 (Figs. 2 and 4). Recess 106 is configured to receive a hexagonal driving head 108 of a surgical instrument that resembles an Allen wrench (Fig. 12).

In use, the intervertebral disk is surgically exposed as described earlier. Once any herniated material that extends out of the intervertebral space is removed, the tapered tip 44 of implant 40 is introduced into the area of herniation in the disc 24 (Fig. 14), with the thread 48 engaging the vertebral body above and below the affected disc. The hexagonal head of

instrument 108 is then introduced into recess 106 of driving end 46 of the implant, and axial force is exerted against the implant in the direction of tip end 44. Simultaneously, body 42 is rotated to advance the implant into the herniated disc and fuse the adjoining vertebral bodies together above and below the disc (Fig. 12).

Desirably, the implant is turned by a tool that includes an implant-retention feature, so the implant doesn't accidentally become disengaged from the tool. Preferably, such a tool is used in conjunction with a guide tube to facilitate placement of the implant and reduce risk of injury. Such details are well known in the art (see, for example U.S. Patent 5,015,247).

As tip 44 impinges against the disc and adjoining vertebral bodies 22a and 22b (Fig. 12), rotation of the implant causes leading edge 52 to approach vertebral body 22a. First indentation 80 comes into contact with body 22a, and as the implant rotates into engagement with bone, the ledge formed by surfaces 86, 88 cuts a recess into the bone such that sharp leading edge 52 can more easily enter into the bone. Further rotation of the implant in a clockwise direction introduces a progressively widening recess 48 into the bone, until second indentation 82 impinges against bone. The sharp edge formed by planar surface 94 of indentation 82 provides cutting action as the implant rotates clockwise, thereby providing further self-tapping action.

Additional clockwise rotation of the implant introduces an even progressively wider portion of thread 48 into the spiral groove already formed by antecedent introduction of more tapered portions of the thread. Third beveled surface 84 moves into the spiral opening, and the edge formed by surface 102 further cuts into the bone to provide a self-tapping function for the threaded implant. Subsequent portions of the thread 48 can then be introduced into the groove formed in the bone by the previous portion of the thread and tapping bevels.

As implant 40 is rotated clockwise (viewed from driving end 46 as in Fig. 5), leading edge 52 impinges against bone in vertebral body 22b, and the same self-tapping process is repeated as described with vertebral body 22a. The length of implant 42 is no longer than the width of the intervertebral disk, such that the distal tip end of the implant will not extend beyond the intervertebral space when the proximal driving end enters the intervertebral space. This feature avoids iatrogenic injury to pre-lumbar spinal structures.

The flared edges of the thread firmly lock the bone to the implant, as shown in Fig. 12. Unlike a conventionally-tapered thread, which would allow the bone to separate from the implant, the radially flared width of the thread provides an enlarged peripheral thread contour that resists disengagement of the thread from the bone. Hence the implant firmly mechanically fuses the adjacent bodies 22a, 22b to one another. The implant is nonetheless capable of being removed by reversing the direction of rotation of the cylindrical body 42.

The described implant is screwed into the vacant space of the disc from which material has been extruded, thereby avoiding the necessity of performing curettage to take any remaining disk material out of the space. Once in place, the implant fuses the adjacent vertebrae on either side of the herniated disc, which maintains normal intervertebral spacing to avoid postoperative disc pinching. The risk of post-operative extradural hematoma is minimized by eliminating the curettage step, which sometime abrades the vertebral plates above and below the herniated disk. Also, the implant tamponades epidural veins, which further reduces the likelihood of hemorrhagic complications. Finally, the implant minimizes the risk of hernial recurrence by closing any trephination orifice through the posterior longitudinal ligament.

Having illustrated and described the principles of the invention in a preferred embodiment, it should be

apparent to those skilled in the art that the invention can be modified in arrangement and detail without departing from such principles. For example, while the invention has been illustrated with reference to a threaded implant, it will be recognized that the implant can be unthreaded, yet employ a similar self-tapping feature. Likewise, while the invention has been illustrated with reference to an insertion procedure that does not require drilling, it will be recognized that in other procedures, a cavity can be drilled prior to insertion of the implant. Still further, while the invention has been particularly described with reference to treating herniated discs, it will be recognized that implants according to the present invention can be used in a number of other surgical procedures as well, some of which have nothing to do with spinal vertebrae. Yet further, while the invention has been illustrated with reference to an inert implant whose outer surface is smooth, it will be recognized that a variety of other arrangements can alternatively be employed, such as the inclusion of hormones or other biological material to foster bone fusion, together with various surface treatments (e.g. porous, textured, etc.) to facilitate bone engagement.

In view of the wide variety of embodiments to which the principles of our invention can be applied, it should be understood that the illustrated embodiments are exemplary only, and should not be taken as limiting the scope of our invention. Rather, we claim as our invention all such embodiments as come within the scope and spirit of the following claims and equivalents thereto.

WE CLAIM:

1. A threaded prosthetic implant, comprising:

an implant including a substantially cylindrical body having a longitudinal axis, a tip and a driving end, wherein the tip tapers along an annular shoulder from a radius equal to that of the cylindrical body down to a lesser radius at a distal end of the implant,

the implant further including a thread extending from the cylindrical body, wherein a width of the thread, where it joins the cylindrical body, is less than a width of the thread at a location radially displaced from said cylindrical body, so engagement of the thread with bone locks the bone to the thread, wherein an outer surface of the thread defines a continuous spiral ribbon along an imaginary cylinder coaxial with the cylindrical body of the implant, said ribbon having a width greater than the width of the thread where it joins the body, and in which the thread defines first and second surfaces coupling the cylindrical body to an outer thread surface, one of said surfaces being nearer the tip end and one of said surfaces being nearer the driving end, said surfaces being compound, with a first portion of the first side surface being parallel to a first portion of the second side surface, and the width of the thread tapers at the distal end of the implant;

and wherein the tip further includes a self-tapping beveled surface in the shoulder, that extends in an imaginary plane intersecting the longitudinal axis of the cylinder, and the self tapping beveled surface extends across the sharp leading edge of the thread.

2. A prosthetic implant comprising:

a substantially cylindrical body with a tip end and a driving end, the cylindrical body defining a longitudinal axis, the implant further including a thread extending from the cylindrical body, wherein the thread tapers to a flat leading surface at the tip end of the body;

wherein the tip defines a self-tapping feature which permits the implant to be inserted without drilling a receiving cavity first, the self-tapping feature comprising an inclined plane that extends across the sharp leading surface.

3. The implant of claim 2 in which the thread defines first and second side surfaces coupling the cylindrical body to an outer thread surface, a first of said surfaces being nearer the tip end and a second of said surfaces being nearer the driving end, the second surface following a spiral track approaching the tip end, the first surface including a portion adjacent the tip end in which said surface is coincident with an imaginary plane perpendicular to the axis of the cylindrical body.

4. The implant of claim 2 in which the tip of the implant tapers, from a radius equal to that of the cylindrical body down to a lesser radius at a distal end of the implant, and in which said tapered tip includes at least one bevelled edge with an exaggerated taper which comprises the inclined plane.

5. The implant of claim 4 in which the tip further defines at least one surface that is in an imaginary plane intersecting the axis of the cylinder, said surface being located where the bevelled edge abuts a portion of the tip without said exaggerated taper.

6. The implant of claim 4 in which the tapered tip defines at least three such bevelled edges.

7. The implant of claim 2 in which the tip of the implant tapers along an annular shoulder that defines an imaginary plane which intersects the longitudinal axis of the cylindrical body, wherein the implant tapers along the shoulder from a radius equal to that of the cylindrical body down to a lesser radius at the tip of the implant, and in which said shoulder includes at least one beveled surface that is in an imaginary plane intersecting the axis of the cylinder, the imaginary plane that defines the beveled surface

being steeper than an imaginary plane that defines the shoulder.

8. The implant of claim 7 in which the tapered tip defines at least three such beveled surfaces, the first beveled surface being the first surface that encounters tissue as the implant is rotated, and the third beveled surface being the last surface that encounters tissue as the implant is rotated.

9. The implant of claim 8, wherein each of the three beveled surfaces is progressively steeper.

10. A method of inserting a prosthesis between two vertebrae of a patient, comprising:

making an incision to gain access to an intervertebral space;

positioning a blunt tip of a self-tapping threaded implant in said region;

rotating said implant, said rotation causing threads on said implant to cut into the two vertebrae; and

closing the incision.

11. The method of claim 10 which further includes the implant cutting into the vertebrae a void shaped to lockingly engage the thread of the implant.

12. A prosthetic implant for placement between two vertebrae of a patient, the implant comprising:

a body having a longitudinal axis, a proximal driving end and a distal tip with a blunt leading surface wherein the body tapers along an annular shoulder to the blunt leading surface;

a continuous helical thread around the body, wherein the width of the thread flares as the thread radially extends away from the body, and the flared width of the thread diminishes as the thread approaches the distal tip to present a flat leading surface at a leading edge of the thread; and

a beveled surface in the shoulder that extends across and intersects the leading edge that cuts into tissue when the implant is rotated.

13. The prosthetic implant of claim 12 wherein the implant is a sterilized implant for surgical placement in the body.

14. The prosthetic implant of claim 12 wherein the body of the implant does not extend radially beyond the helical thread around the body.

15. The prosthetic implant of claim 12 wherein the beveled surface is in an imaginary plane which is steeper than the shoulder and which intersects the longitudinal axis of the body.

16. The prosthetic implant of claim 12 further comprising a recess in the proximal driving end, into which a driving instrument can be placed to rotate the implant.

17. The prosthetic implant of claim 12, further comprising a second beveled surface in the shoulder that is steeper than the shoulder, and intersects the thread.

18. The prosthetic implant of claim 17, further comprising a third beveled surface in the shoulder that is steeper than the shoulder, and intersects the thread.

19. The prosthetic implant of claim 12, wherein the tip comprises a nose surface that is substantially flat and perpendicular to the longitudinal axis of the body.

20. The prosthetic implant of claim 16 wherein the recess is shaped to retain an instrument that is inserted into the recess, to avoid inadvertent dislodgement of the implant from the instrument.

21. A prosthetic implant for placement in an intervertebral space between two vertebrae of a patient, the implant comprising:

a body having a longitudinal axis, wherein the body tapers along a shoulder to a distal tip with a flat nose surface that is substantially perpendicular to the longitudinal axis of the body;

a recess in the proximal driving end, into which an instrument can be inserted to rotate the body;

a continuous helical thread around the body, wherein the width of the thread flares as the thread radially extends away from the body, and the flared width of the thread diminishes as the thread approaches the distal tip to present a flat leading surface at a leading edge of the thread; and

first, second and third beveled surfaces in the shoulder, wherein each surface extends across and intersects the helical thread or leading edge to present a surface perpendicular to and through the thread, wherein the surfaces are substantially equally spaced around the shoulder and form a sharp edge that cuts into tissue as the implant is rotated.

22. The implant of claim 21 wherein the recess in the driving end has a polygonal shape.

23. A method of placing a spinal implant into an intervertebral space between two vertebrae of a patient, comprising the steps of:

providing an implant comprising a body having a longitudinal axis, wherein the body tapers along a shoulder to a distal tip with a blunt nose surface, and the body includes a continuous helical thread around the body, wherein the width of the thread flares as the thread radially extends away from the body, and the flared width of the thread diminishes as the thread approaches the distal tip to present a flat leading surface at a leading edge of the thread; and

placing the distal flat nose surface against a disc between two vertebrae, and rotating the body to drive the implant into the intervertebral space.

24. The method of claim 23 wherein the implant further comprises a recess in the driving end of the body, and the method further comprises the step of inserting an instrument into the recess to rotate the implant and advance it into the intervertebral space.

FIG. 1

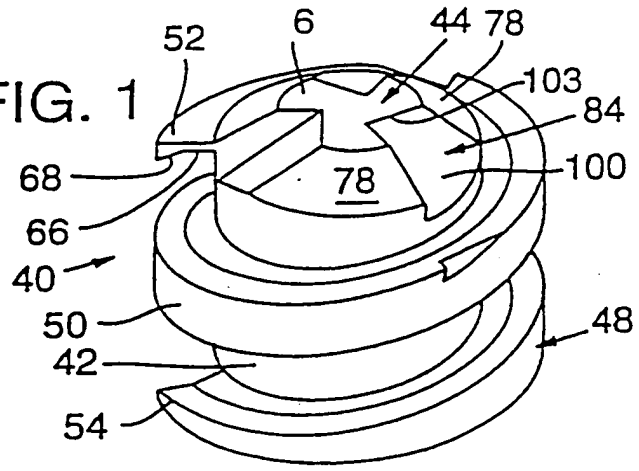


FIG. 2

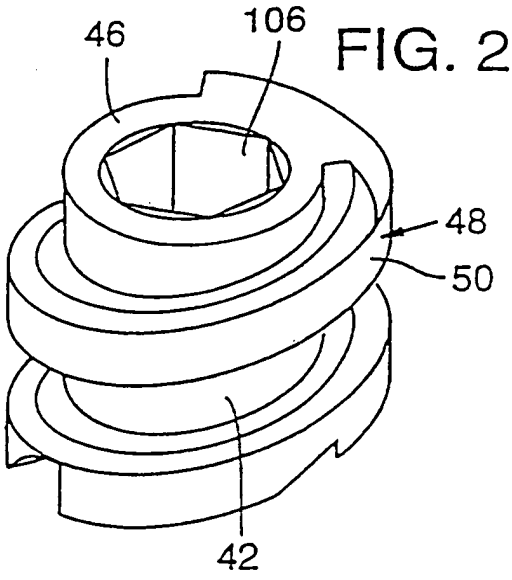


FIG. 3

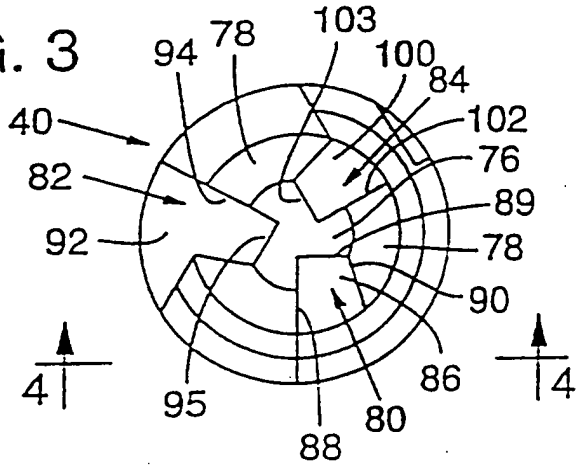


FIG. 13

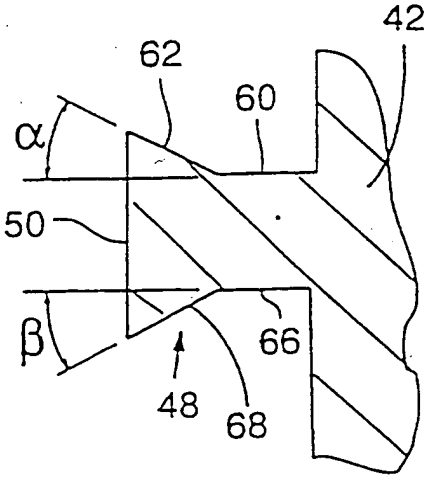


FIG. 4

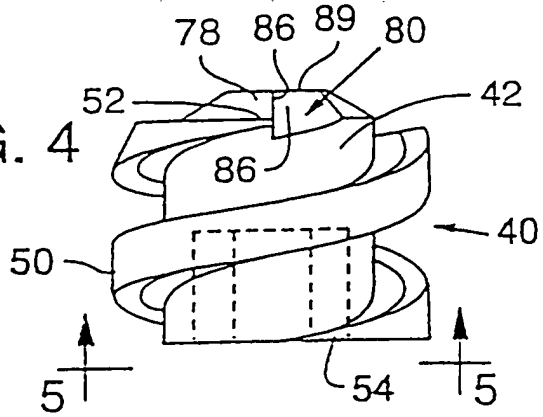


FIG. 5

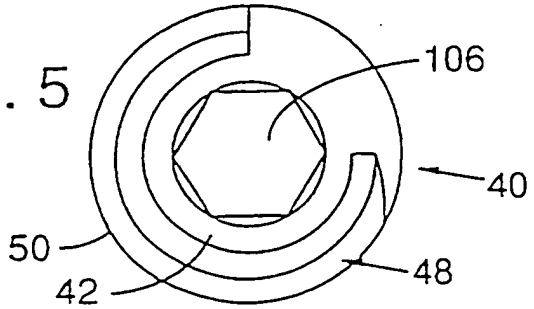


FIG. 6

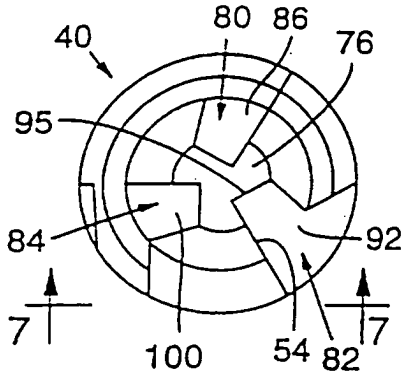


FIG. 8

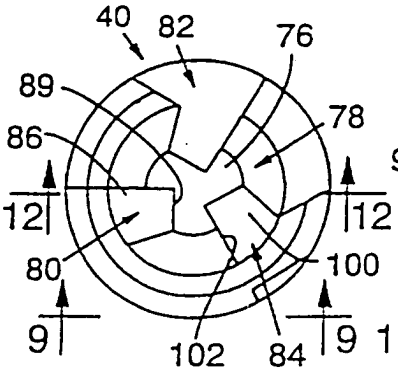


FIG. 10

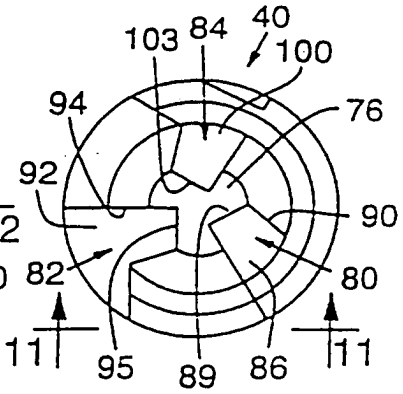


FIG. 7

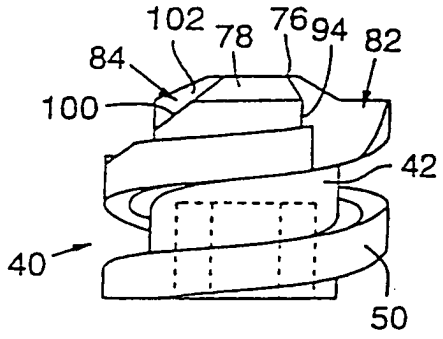


FIG. 9

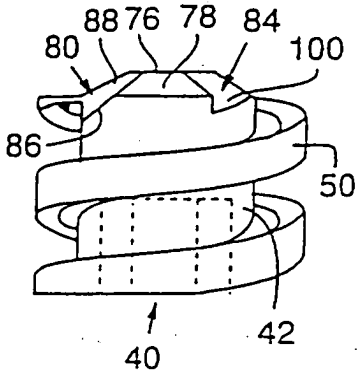


FIG. 11

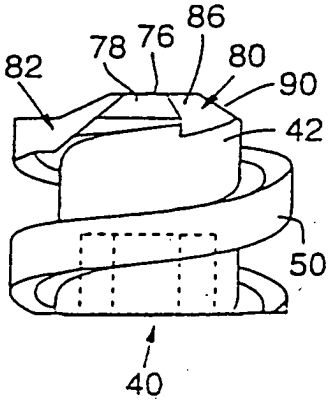


FIG. 12

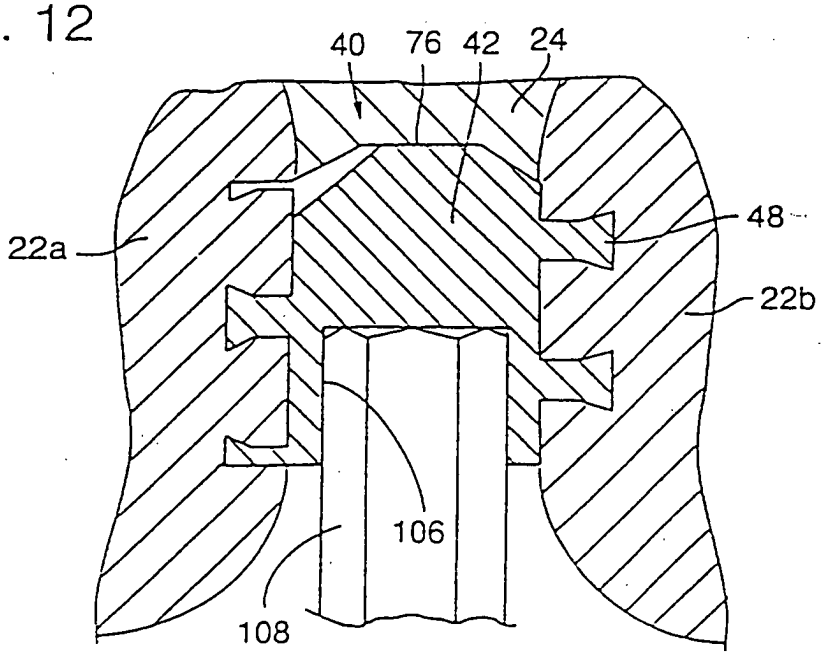
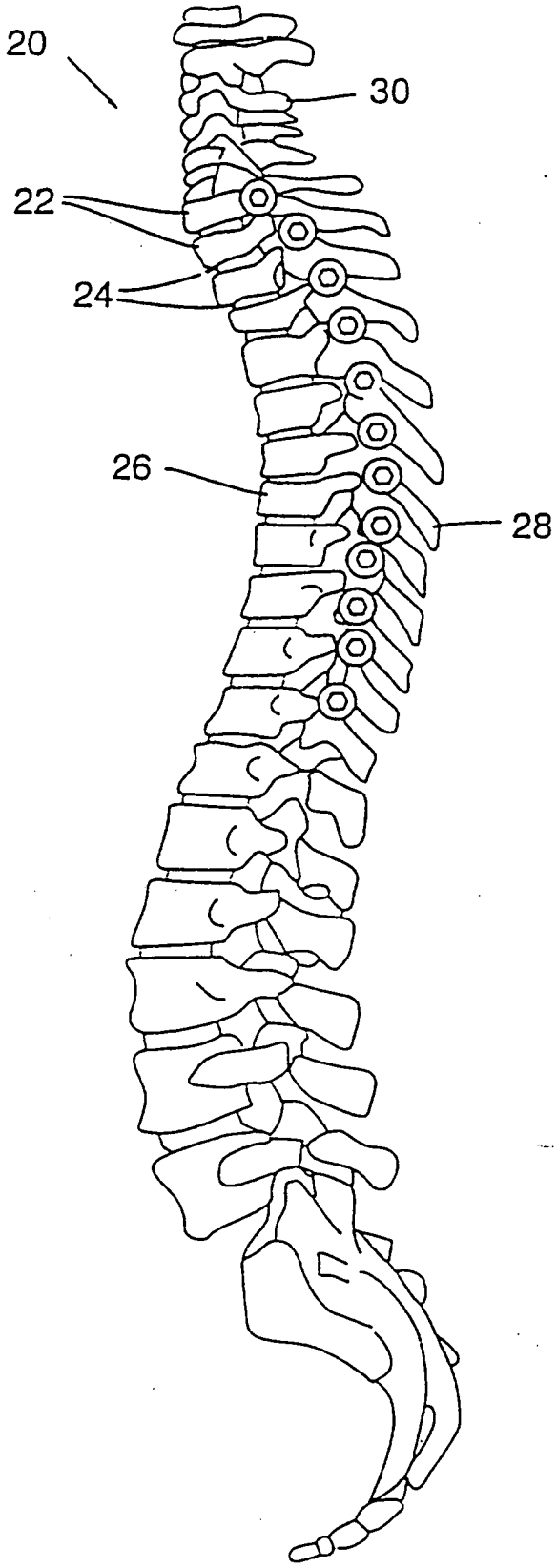


FIG. 14



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/03226

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/68; A61F 2/44
US CL :606/73; 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 411/311, 387, 389, 394, 411, 414, 423, 426; 606/61, 73; 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4878915 (BRANTIGAN) 07 November 1989, see Fig. 9, and column 6 lines 44-51.	10, 11, 23, 24
Y	GB, A, 566,907 (AMERICAN SCREW COMPANY) 18 January 1945, see Figs. 5, 6, 10 and 18, page 3 line 108, page 6 line 60, et seq.	2-9
Y	CH, A, 321629 (BROGIOTTI) 29 June 1957, see entire document.	2-9

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 28 MAY 1996	Date of mailing of the international search report 11 JUN 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DAVID H. WILLSE Telephone No. (703) 308-2903

Form PCT/ISA/210 (second sheet)(July 1992)*